

## United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
09/690,198	10/16/2000	Douglas A. Collins	COP1002	2250
7	590 11/27/2001			
Sherry Knowles KING & SPALDING 191 Peachtree Street N E			EXAMINER	
			WILLIS, MICHAEL A	
45th Floor Atlanta, GA 30303			ART UNIT	PAPER NUMBER
	.0505		1619	
			DATE MAILED: 11/27/2001	

Please find below and/or attached an Office communication concerning this application or proceeding.

:	Application No.	Applicant(s)				
	09/690,198	COLLINS ET AL.				
Offic Action Summary	Examiner	Art Unit				
	Michael A. Willis	1619				
The MAILING DATE of this communication appears on the cover sheet with the corresp indence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status						
1) Responsive to communication(s) filed on	·					
2a) ☐ This action is <b>FINAL</b> . 2b) ☑ Th	is action is non-final.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
4)⊠ Claim(s) <u>1-120</u> is/are pending in the application.						
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6) Claim(s) is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) 1-120 are subject to restriction and/or election requirement.						
Application Papers						
9)☐ The specification is objected to by the Examiner.						
10) The drawing(s) filed on is/are: a) □ accepted or b) □ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved by the Examiner.						
If approved, corrected drawings are required in reply to this Office action.						
12) The oath or declaration is objected to by the Examiner.						
Priority under 35 U.S.C. §§ 119 and 120						
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a) All b) Some * c) None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.						
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).						
a) ☐ The translation of the foreign language provisional application has been received.  15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.						
Attachment(s)						
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)	5) Notice of Informal F	(PTO-413) Paper No(s) Patent Application (PTO-152)				

Page 2

Application/Control Number: 09/690,198

Art Unit: 1619

## **DETAILED ACTION**

## Election/Restrictions

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - Claims 1-112, drawn to cobalamine compounds, classified in class 514, subclass 52.
  - II. Claims 113 and 114, drawn to the use of a cobalamine compound for the manufacture of a medicament for imaging, classified in class 514, subclass 52.
  - III. Claims 115 and 116, drawn to the use of a cobalamine compound for the manufacture of a medicament for treating a tumor, classified in class 514, subclass 52.
  - IV. Claims 117 and 118, drawn to a method of treating a tumor, classified in class 424, subclass 9.2.
  - V. Claims 119 and 120, drawn to a method of imaging a tumor, classified in class 424, subclass 9.2.

The inventions are distinct, each from the other because of the following reasons:

2. Invention I is related to Inventions II-V as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product can

Application/Control Number: 09/690,198 Page 3

Art Unit: 1619

be used in a variety of materially different processes, such as the manufacture of a medicament for imaging, the manufacture of a medicament for treating tumors, for a method of treating a tumor, or for a method of imaging a tumor.

- 3. Inventions II-IV are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. For instance, a process of manufacture of a medicament for imaging a tumor has a different mode of operation from a method of manufacture of a medicament for treating a tumor, and both manufacturing methods are different from methods of imaging a tumor or methods of treating a tumor.
- 4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.
- 5. Claims 1-120 are generic to a plurality of disclosed patentably distinct species comprising derivatives of formula I. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. By single species is meant a single compound. The compound may be named in any of four ways: 1) according to IUPAC standard, 2) by a pictorial representation of the compound, 3) by setting forth the specific chemical group that each variable of the Markush group

Application/Control Number: 09/690,198

Art Unit: 1619

represents, or 4) by naming a claim or an example which itself sets forth a single compound.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

In the event that the Markush-type claims are not found to be allowable, the examination of the claims presented will be limited to the extent that they read on the elected species and claims directed solely to the elected species. The claims directed solely to the non-elected species will be held withdrawn from consideration.

- 6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined and an election of species even though the requirement be traversed (37 CFR 1.143).
- 7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Application/Control Number: 09/690,198

Art Unit: 1619

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael A. Willis whose telephone number is (703) 305-1679. The examiner can normally be reached on Mon. to Fri. from 9 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana L. Dudash can be reached on (703) 308-2328. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-2742 for regular communications and (703) 308-2742 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Michael A. Willis

Midge Dhilles

Page 5

Examiner Art Unit 1619

November 20, 2001

MICHAEL G. HARTLEY PRIMARY EXAMINER